

### **REMARKS**

Applicants respectfully request further examination and reconsideration in view of the above amendments and the arguments set forth fully below. In the Office Action mailed June 6, 2008, claims 1-20 have been rejected. In response, the Applicants have submitted the following remarks, amended claims 1, 4, 6, 16 and 20, and cancelled claim 3. Accordingly, claims 1-2 and 4-20 are now pending. Favorable reconsideration is respectfully requested in view of the amended claims and remarks below.

#### **Examiner Interview Summary**

On September 5, 2008, Examiner Natasha Patel and the undersigned conducted a brief telephonic examiner interview. The undersigned wishes to thank the Examiner for her willingness to interview this case on short notice and for her kind attention to this application. During the interview, the undersigned and the Examiner discussed the independent claim 1 and the rejection of the same under 35 U.S.C. §102(b) as being anticipated by Malik. The undersigned proposed some arguments and related amendments to the Examiner. While no agreement was reached, the Examiner indicated there may be aspects of the invention that are novel over the cited prior art. The above amendments are made in response to this discussion. Again, the Applicants wish to thank the Examiner for her kind attention and willingness to interview this case.

#### **Rejections Under 35 U.S.C. §102**

Claims 1, 2, 3, 6, 8, 15, 17-18 and 20 have been rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 6,438,409 to Malik et al. (hereinafter Malik). The Applicants respectfully disagree with this rejection.

The Malik reference teaches methods of characterizing ventricular operations and applications regarding the same. The Malik reference, while utilizing optimally constructed orthogonal systems to represent the 12 lead ECG, that which the Examiner characterizes as a template, shows ECG recordings being used in a study [Malik, column 14, lines 10-28], exemplifying this template. However, Malik does not teach the concept of trending in detecting cardiac repolarization abnormality. That is, the Malik reference does not teach

creating a template from one or more of the representative beats collected from the patient, and comparing each subsequent representative beat to this template for variations. The variations that are derived from this comparison in the present application are compared to a set of threshold values, which are derived from a serial ECG analysis of the patient, and not from a study. The template of the present application, unlike Malik, is then adjusted based on the variation. As was discussed in the telephone interview with Examiner Patel, the teachings discussed above can be found in the present application, paragraphs 27, 29 and 30.

The Cohen reference was utilized by the Examiner to teach using thresholds in conjunction with the template comparison in the Examiner's subsequent rejection of independent claims 16 under 35 U.S.C. §103(a). While Cohen may disclose checking for abnormalities by checking a variation between the template and the at least one value corresponding to at least one other of the representative beats is greater than a threshold value, Cohen does not teach the trending concept as discussed and now claimed in the present application. That is, Cohen does not teach comparing a variation to a threshold value that is derived from a serial ECG analysis of the patient and adjusting the template based on the variation. Therefore, Cohen also does not teach the concept of trending as described and claimed and argued in this Office Action response.

In contrast to the teachings of Malik and Cohen, the present application, as discussed above, as numerous ECG signals are analyzed in the present application, threshold levels can be established for the various values representing the representative beats. When one or more threshold levels are exceeded, the patient may be a candidate for further testing [present application, paragraph 27]. Once the template is derived from one or more of the representative beats, it is compared to each subsequent representative beats for variations. The variations are compared to a threshold value that is derived from a serial ECG analysis, and the template is adjusted based on the variation. This analysis and adjustment of a template over time is not taught in either Malik or Cohen. The Applicants respectfully submit that this concept of trending in detecting cardiac repolarization abnormality is novel and renders the claims non-obvious over the cited prior art.

The independent claim 1 is directed to a method of detecting cardiac repolarization abnormality using at least one electrocardiogram signal, the method comprising: deriving a

total quantity of representative beats of the at least one electrocardiogram signal taken from a patient ECG; using at least one morphology shape descriptor to determine a total quantity of values representing the total quantity of representative beats; generating a template using at least one value corresponding to at least one of the representative beats; comparing the template and at least one value corresponding to at least one other of the representative beats for a variation; and comparing the variation to a threshold value, wherein the threshold value is derived from trending, further wherein trending includes a time serial analysis; using data corresponding to at least some of the total quantity of values to assess cardiac repolarization abnormality in the patient. As discussed above, Malik does not teach creating a template from one or more of the representative beats, comparing each subsequent representative beat to this template for variations, comparing the variations to a threshold value, wherein the threshold value is derived from a serial ECG analysis, and adjusting the template based on the variation. For at least these reasons, the independent claim 1 is allowable over the teachings of Malik.

Claims 16 and 20 have been amended to include similar limitations to that of the independent claim 1. As discussed above, the independent claim 1 is allowable over the teachings of Malik, and also over the teachings of Malik, Cohen and their combination. Accordingly, claims 16 and 20 are also allowable for the same reasons as discussed above with respect to the independent claim 1.

Claims 2, 6, 8, 15, 17 and 18 are dependent upon the independent claims 1 and 16. As discussed above, the independent claims 1 and 16 are allowable over the teachings of Malik. Accordingly, claims 2, 6, 8, 15, 17 and 18 are also allowable as being dependent upon an allowable base claim. Claim 3 has been cancelled.

*Rejections Under 35 U.S.C. §103*

Claims 4, 5, 7, 11 and 16 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Malik in view of Cohen. As discussed above, neither Malik, Cohen nor their combination teach the concept of trending in determining cardiac repolarization abnormality. As further discussed above, this renders the independent claim 16 allowable over the teachings of Malik, Cohen and their combination.

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Claims 4, 5, 7 and 11 are dependent upon the independent claim 1. As discussed above, the independent claim 1 is allowable over the teachings of Malik. Accordingly, claims 4, 5, 7 and 11 are also allowable as being dependent upon an allowable base claim.

Claims 9-10 and 19 have been ejected under 35 U.S.C. §103(a) as being unpatentable over Malik in view of U.S. Patent No. 6,847,840 to DePasquale et al. (hereinafter DePasquale). Claims 9-10 and 19 are dependent upon the independent claims 1 and 16. As discussed above, the independent claims 1 and 16 are allowable. Accordingly, claims 9-10 and 19 are also allowable as being dependent upon an allowable base claim.

Claims 12-14 have been ejected under 35 U.S.C. §103(a) as being unpatentable over Malik in view of Cohen as applied to claim 11, and further in view of U.S. Patent No. 6,983,183 to Thiagarajan et al. (hereinafter Thiagarajan). Claims 12-14 are dependent upon the independent claim 1. As discussed above, the independent claim 1 is allowable over Malik/Cohen. Accordingly, claims 12-14 are also allowable as being dependent upon an allowable base claim.

For these reasons, Applicants respectfully submit that all of the claims are now in a condition for allowance, and allowance at an early date would be appreciated. Should the Examiner have any questions or comments, they are encouraged to call the undersigned at 414-271-7590 to discuss the same so that any outstanding issues can be expeditiously resolved.

Respectfully submitted,

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